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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/852,020 05/06/97 MARUYAMA

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HM12/1022

THE SCRIPPS RESEARCH INSTITUTE
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EXAMINER

LEFFERS JR, G

ART UNIT

PAPER NUMBER

1636

17

DATE MAILED:

10/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/852,020

Applicant(s)

MAYUYAMA, ET AL

Examiner

LEFFERS

Group Art Unit

1636

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 8/2/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/852,020 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment entered on 8/2/99 has been entered. Claims 30-56 have been canceled and claims 57-60 have been added.

Specification

2. The disclosure is objected to because of the following informalities: The address for the ATCC has changed, pages 133-134 should be amended to provide the new address.

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Appropriate correction is required.

Claim Objections

2. Claim 57(e) is objected to in that "suppresor" is misspelled.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 57, the claim is vague and indefinite as written because the use of the phrase "...for expression of a matrix anchor and a fusion protein that comprises:..." makes it unclear as to whether pV, which is specified in the claim as encoded by the first upstream translatable sequence on the vector is in fact the "matrix anchor" of the fusion protein, or whether it is merely part of the fusion protein which is displayed on the phage. The term "matrix anchor" is not clearly linked to the pV tail polypeptide in the rest of the body of the claim. The use of the term "and" in the phrase above implies that the matrix anchor is somehow distinct from the fusion protein and the use of the term "comprises" before further limiting the make-up of the fusion protein to including pV, a linker and a selected fusion protein suggests the possibility that some other phage-matrix protein may serve as the matrix anchor. It is suggested that clearly linking pV to the term matrix anchor and changing the term "comprising" in the phrase above to "consisting of" would be remedial. Because the specification appears to teach that pV is intended

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to serve as the matrix anchor, claims 57 and 58 were further examined as though the claims clearly specify pV as the matrix anchor.

With regard to claim 59, the claim is vague and confusing in that the term "matrix anchor" is not clearly linked to pV, leaving the possibility that the preselected polypeptide that forms the remainder of the fusion protein described in the claim has its own potential matrix anchor sequence. It is suggested that more definitively linking the term "matrix anchor" to pV would be remedial for claim 59. Claims 59 and 60 were further examined with the view that claim 59 does specify pV as the matrix anchor for the fusion polypeptide.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 57 and 58 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of U.S. Patent No. 5,627,024. This is a double patenting rejection.

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Claim 57 has changed the phrase "(ii) encodes a conditionally suppressible cistron for expression of a **tail protein**....." from claim 1 of U.S. Patent No. 5,627,024 to "(ii) encodes a conditionally suppressible cistron for expression of a **matrix anchor**..." (emphasis added by examiner). Also, the phrase from claim 1(e) "...to form a fusion polypeptide consisting of said **tail polypeptide**...." has been changed to "...to form a fusion polypeptide consisting of said **pV polypeptide**....". In each case the terms tail protein, matrix anchor and pV polypeptide are synonymous since it is the pV polypeptide which is a lambdoid tail protein serving as an anchor for fusion polypeptides displayed on the surface of the phage tail in this system. The metes and bounds of the original claims in U.S. Patent No. 5,627,024 are not changed in any way by the changes in phrasing found in claim 57 of this application and thus the invention claimed in claims 57-58 are identical to the claims of '024.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59 and 60 are rejected under the judicially created doctrine of double patenting over claims 9 and 11 of U. S. Patent No. 5,627,024 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: claim 9 of U.S. Patent No. 5,627,024 specifies "...and said fusion protein **comprising**, in the direction of the amino terminus to carboxy terminus, a pV lambdoid bacteriophage tail polypeptide, a linker polypeptide and a preselected polypeptide." (examiner's emphasis). Claim 59 of the instant application changes the term "**comprising**" to "**consisting of**" thereby narrowing the scope of claim 59 to include only the limitations specified in the remainder of claim 9 of the issued patent. Thus, because "comprising" totally encompasses "consisting of" of the same recited components, it covers the subject matter claimed in the instant application.

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Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014.

NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The

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examiner can normally be reached on Monday through Friday, from about 7:00AM to about 3:30PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

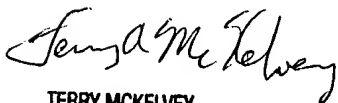
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



G. Leffers, Jr.

Patent Examiner

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TERRY MCKELVEY
PRIMARY EXAMINER

October 21, 1999